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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------------|------------------------------------|
| 09/784,980 | 02/16/2001 | Anthony John Bell | 5641C1-07-LAV | 5253 |
| <div>7590 Allen R. Kipnes, Esq. WATOV & KIPNES, P.C. P.O. Box 247 Princeton Junction, NJ 08550</div> | | | <div>EXAMINER CHAWLA, JYOTI</div> | |
| | | | <div>ART UNIT 1761</div> | <div>PAPER NUMBER</div> |
| | | | <div>MAIL DATE 06/07/2007</div> | <div>DELIVERY MODE PAPER</div> |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 09/784,980 | Applicant(s) BELL ET AL. | |
| | Examiner Jyoti Chawla | Art Unit 1761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 2, 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 and 46-55 is/are pending in the application.
- 4a) Of the above claim(s) 10-27 and 46-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 28-36 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed on February 26, 2007 has been entered. Claims 1-36 and 46-55 are pending in the application. Claims 10-27 and 46-54 were withdrawn from further consideration as being directed to a non-elected invention. Claims 1-9, 28-36 and 55 are examined in the present office action.

Claim Objections

Claim 7 is objected to because of the following informalities: The claim has wrong dependence as it depends on claim 7. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 28 and 55 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "a chemically induced unpleasant mouthfeel" was not described in the specification. Applicant's arguments regarding the rejection of "chemically induced unpleasant mouthfeel" have been considered but have not been found persuasive.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 28 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 28 and 55 remain rejected for the recitation of the term "a chemically induced unpleasant mouthfeel" for the reasons of record. Applicant's arguments (Remarks page X) have been fully considered, however, it is unclear as to what constitutes "unpleasant mouthfeel" as recited. Unpleasant mouthfeel could be due to the taste of the product (e.g., bitter, sour, burning sensation on the tongue, tongue tingling, etc.), chewing characteristics of the product, texture of the product or added chemical (e.g., grittiness or stickiness, etc.) Also, the term "unpleasant mouthfeel" is indefinite as a food or flavor that might have unpleasant mouthfeel for some, would be desirable for others. The invention as claimed addresses the suppression of unpleasant mouthfeel caused by the botanicals. Thus applicant's arguments have not been found persuasive and the rejection is maintained for reasons provided herein and in the previous office action dated September 20, 2006.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(A) Rejection of claims 1, 2, 4-9, 28, 29, 31-36 and 55 under 35 U.S.C. 103(a) as being unpatentable over Katsuragi et al. (EP 0732064 A1) in view of the combination of Sharma et al (US 4797288) and Oravainen (WO9107100) has been withdrawn based on applicant's arguments.

(B) Rejection of claims 3 and 30 under 35 U.S.C. 103(a) as being unpatentable over Katsuragi in view of the combination of Sharma and Oravainen as applied to claims 1, 2, 4-9, 28, 29, 31-36 and 55 above, further in view of either Raymont (AU 9671904 A) or

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Emanuel–King (US 5248503) has been withdrawn based on applicant's arguments.

(C) Claims 1, 2, 4-9, 28, 29, 31-36 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsuragi et al. (EP 0732064 A1) in view of Seang et al (WO 94/05260).

Katsuragi et al., hereinafter Katsuragi, teaches a bitterness relieving agent for food, medicine, cosmetic uses. Katsuragi teaches adding at least one botanical, such as Ginkgo biloba to lozenges (Claims 2, 29), or hard-boiled candies, troches etc., and providing a bitterness-relieving agent to suppress the unpleasant mouthfeel associated with a botanical (Page 4, lines 9-10, 26-37 and 57), as recited in claims 1, 2, 28, 29 and 55. Katsuragi teaches that the bitterness-relieving agent comprises an ester of a glyceride (mono/di-glyceride and triglycerides, i.e., fats and oils) with a carboxylic acid (e.g., citric acid is a polycarboxylic acid) or salt thereof. Katsuragi teaches that the preferred fatty acids (either saturated or unsaturated) range from 8-22 carbon atoms, including lauric acid, stearic acid, oleic acid, linoleic acid and linolenic acid (Page 3, lines 3-20). Katsuragi further teaches that bitterness relieving agent can be dissolved in edible oils (hydrogenated, transesterified or regular), such as palm kernel oil, milk fat and cottonseed oil to name a few, before being added to food (Page 3, line 58 to Page 4, line 7) as recited by the applicant 1, 4, 5, 28, 31, 32, 55. Thus Katsuragi teaches a fat soluble bitterness relieving composition using esterified fatty acids with glycerol, and polycarboxylic acid (e.g., citric acid). Regarding the amount of bitterness relieving agent as recited in claims 1, 6, 7, 28, 33, 34 and 55, or ester, Katsuragi teaches that 0.01-10% of the compound is effective to suppress the unpleasant mouthfeel of the botanical (Page 4, line 42-45), by dissolving the ester in the oil, the resulting oil becomes effective to suppress the unpleasant mouthfeel. Thus Katsuragi teaches of lipid based compound as a bitterness relieving agent, however, the reference does not explicitly teach the quantity of oil that is effective to suppress the unpleasant mouthfeel as recited in claims

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1,6-9,28,33-36 (See Abstract, Page 3, lines 9-13, Page 3, line 58 to Page 4, line 5, Page 4, lines 25-47, Examples 3 and 4, Claims).

Since the effect of lipids in masking the unpleasant taste (e.g., bitterness) in the pharmaceutical compositions has been known in the art, therefore, to select any particular level of the effective oil, such that the level is 0.5-5%, 0.5-3.5%, or 0.75 to 3.0% in the hard candy as recited in claims 1, 6, 7, 28, 33, 34 and 55 would have been obvious depending on the bitterness of the botanical included, and also depending on the amount of botanical included. Thus one of ordinary skill in the art at the time of the invention would have been motivated to look to the art for specific lipids and the relative amounts of the lipids that would be effective in suppressing the unpleasant flavor or taste of a botanical or a pharmaceutical drug in the edible composition.

Seang et al., hereinafter Seang, teaches that lipid coating on certain drugs has been beneficially employed to mask the bitter taste (Page 1, line 28 to Page 2, line 2). The reference also teaches that the lipid can be a saturated or unsaturated fat, or hydrogenated or partially hydrogenated oils, such as, cottonseed oil, castor oil, coconut oil or waxes (Page 6, lines 1-15 and pages 6-8) to mask the unpleasant taste and flavor of the pharmaceutical component (Claim 4, 5, 31, 32). Regarding the ratio of the saturated fats or hydrogenated oil to the botanical (pharmaceutical drug, minerals, botanicals etc.), Seang teaches a ratio of lipid to botanical is 0.25:1:0 to 2:1 (Page 8, lines 5-10), which includes the range recited by the applicant in claims 8, 9, 35, and 36. Regarding the amount of lipids in the composition Seang teaches 400mg of lipid (PURECO) in the total composition of 12.275 grams, i.e., the lipid component is 3.2% (Page 9-10, Inventive Examples 1-3) and about 2.1% (i.e., 267mg lipid in the total composition of 12.627 grams) (Page 11, Inventive Example 5), which fall in the recited range of the applicant in claims 1, 6, 7, 28, 33, 34 and 55. Thus the use of saturated fats and hydrogenated or partly hydrogenated oils in the amount recited by the applicant was known in the art for its function of masking the unpleasant flavor and reduce bitterness as taught by Seang. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Katsuragi's composition and add saturated fats or hydrogenated or partially hydrogenated fats in the amount taught by

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Seang, for their known function of masking the unpleasant flavor and bitter taste (Seang, page 1, line 28 to page 2, line 2 and examples 1-5). One would have been further motivated to do so in order to make the candy composition comprising a botanical more economically by using commonly available edible lipids and also more acceptable to the consumers.

(D) Claims 3 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsuragi in view of Seang as applied to claims 1, 2, 4-9, 28, 29, 31-36 and 55 above, further in view of either Raymont (AU 9671904 A) or Emanuel-King (US 5248503).

Katsuragi teaches Ginkgo biloba added to lozenges/troches, but is silent in teaching a hard candy with Echinacea. Raymont and Emanuel King have been relied on as evidence of the conventionality of adding Echinacea to lozenges/troches/ breath dots etc. Raymont teaches the combination of active ingredients has a significant synergistic effect such that the therapeutic effect is greater than a merely additive effect. In particular, Raymont teaches that Echinacea provides immune system benefits (Page 2, lines 7-12, Page 3, lines 10-31, Page 5, line 22). Therefore, to include Echinacea would have been an obvious matter of choice, depending on the desired benefit of the botanical (e.g. improving the immune system). One would have been substituting one conventional botanical for another for the same purpose: providing a medical benefit in a hard candy form. One would have been further motivated include Echinacea to the troches or candy, to benefit from the synergistic effect of Ginkgo and Echinacea.

Response to Arguments

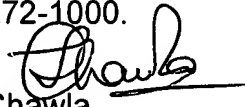
Applicant's arguments submitted February 26, 2007 regarding the rejection have been fully considered but are moot in view of the new ground(s) of rejection. Applicant is referred to the rejection above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Chawla whose telephone number is (571) 272-8212. The examiner can normally be reached on 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jyoti Chawla
Examiner
Art Unit 1761


KEITH HENDRICKS
PRIMARY EXAMINER